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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,003	09/09/2003	Frank N. Chang	06056-0314 US1	3509
23973 7590 02/21/2007 DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996			EXAMINER OLSEN, KAJ K	
			ART UNIT 1753	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	02/21/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/659,003	Applicant(s) CHANG ET AL.	
	Examiner Kaj K. Olsen	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 70-82 is/are allowed.
- 6) ☒ Claim(s) 1-5,8-10,15-32,34-69 and 83-92 is/are rejected.
- 7) ☒ Claim(s) 6,7,11-14 and 33 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8-12-04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. In claims 40 and 41, there is no antecedent basis for “the at least one electrophoresis *unit*” (emphasis added). Presumably, claims 40 and 41 should depend from claim 39, which did disclose an electrophoresis unit.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5, 8-10, 15-32, 37-39, 41, 43-48, 63-66, and 83-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong et al (Hwahak Konghak, 29(4), 1991, pp. 457-462) in view of Harrington et al (USP 5,637,202). The examiner has requested a translation of Hong, which should be available by March 20, 2007.

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6. Hong discloses an electrophoresis system and method for the separation of proteins comprising a low conductivity organic solvent comprising at least one base solvent (propylene glycol, propylene carbonate), and at least one conductivity enhancer (N-methylacetamide, tetrahydrofuryl alcohol). Hong also discloses the use of a polymeric membrane (i.e. paper) that is compatible with the low conductivity organic solvent, and an electrophoresis apparatus which comprises at least one electrophoresis unit for containing the buffer and membrane and a power supply capable of generating an electric current in the at least one electrophoresis unit. See the abstract, fig. 1 and sections 2.1 and 2.2. Hong does not explicitly disclose that the paper has a high-protein binding capacity. Applicant suggests on p. 4, ll. 4-10 that conventional electrophoresis papers do not possess high protein binding, Lederer actually evidences that the protein-binding qualities of electrophoresis paper can vary greatly with some papers having rather substantial protein binding. See p. 28. However, to the applicant's benefit, the examiner will presume the filter paper utilized by Hong would not meet the applicant's claimed high-protein binding. However, Harrington teaches that paper electrophoresis papers have been found lacking in the prior art and proposes the use of other polymeric membranes that have more uniform pore sizes and distributions providing for more accurate and reproducible electrophoretic separations. See col. 1, ll. 29-36 and col. 3, ll. 42-54. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Harrington for the system of Hong in order to provide an electrophoretic medium providing higher accuracy and reproducibility. With respect to the membranes Harrington providing high-protein binding, Harrington's preferred membrane is polyvinylidene difluoride

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(PVDF), which the instant invention evidences has high-protein binding capabilities (see claim 29).

7. With respect to the presence of a conductivity suppressor, Hong relies on a combination of two different base solvents. See section 2.1. Whichever of these two materials (ethylene glycol or propylene carbonate) has the lower inherent conductivity would thereby read on the defined conductivity suppressor because this solvent would have the effect of lowering the conductivity of the buffer.

8. With respect the use of between 5-30% of this conductivity suppressor, in the absence of any criticality to Hong's use of 40-40 percentages of each of these solvents, the use of other ratios, such as 50-30, etc would have required only routine skill in the art.

9. With respect to claims 18-21, these claims only further limit claim 1 when the addition of a conductivity suppressor is explicitly recited (in claim 1, it is merely optional). Because claim 18 does not explicitly recite that the suppressor is present (like claim 17 does), these claims currently do not further limit claim 1.

10. With respect to the use of hydrophobic or hydrophilic membranes, see Harrington, col. 3, ll. 55-60.

11. With respect to the various protein-binding concentrations, because Harrington's preferred membrane (PVDF) is the same material disclosed by the instant invention (claim 29), it would inherently meet these limitations.

12. With respect to claims 31 and 32, this claim only further limits claim 28 when polyesters or vinyl polymers are chosen from the groupings. Because claims 31 and 32 do not actually

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require polyester or vinyl polymer be chosen from the groupings, these claims do not further limit claim 28 when fluorinated polymers are chosen from claim 28.

13. With respect to the membrane thickness, see Harrington, col. 5, ll. 42-47.

14. With respect to a plurality of electrophoresis units, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a plurality of electrophoretic units, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

15. With respect to the use of horizontal electrophoresis, see fig. 1 of Hong.

16. With respect to the use of second dimensional electrophoresis, see Harrington, col. 8, ll. 22-36.

17. With respect to the use of non-denaturing conditions and the detecting of enzymatic activity, Hong discloses that the organic buffer did not affect the activity of the protein. See the abstract. Hence, the solvent did not denature the protein. With respect to how the activity was determined, the use of standard means for determining protein activity requires only routine skill in the art.

18. With respect to the specified current levels, because the organic buffer of Hong overlaps the buffer of the claims (see discussion above), the method of Hong and Harrington would have inherently resulted in the set forth current ranges.

19. With respect to the claims drawn to separating the proteins according to their isoelectric points, these claims have the same scope as the earlier method claims. With respect to the separation being according to their isoelectric points, first, applicant has no step or steps drawn to performing an actual isoelectric separation. Second, because the buffer utilizes by the instant

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invention is so similar to the buffer disclosed by Hong, the solvent is Hong would have inherently resulted in an isoelectric separation regardless of whether Hong recognized that at the time.

20. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong and Harrington as applied to claim 24 above, and further in view of Hiratsuka et al (USP 4,128,470).

21. The references set forth all the limitations of the claims, but did not explicitly set forth any of the listed polymers. Hiratsuka discloses in an alternate electrophoresis system that nylon can also be utilized as an electrophoretic support. See example 3 at col. 8, l. 56 through col. 9, l. 4. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Hiratsuka for the system of Hong and Harrington because the substitution of one known electrophoretic support for another requires only routine skill in the art. With respect to the use of particular concentrations of amine termination, because Hiratsuka relies on a alcohol soluble form of nylon, the use of amine-terminated nylon would have been obvious so as to facilitate that solubility.

22. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hong and Harrington as applied to claim 1 above, and further in view of Bambeck et al (USP 4,909,918).

23. The references set forth all the limitations of the claims, but did not explicitly recite the use of vertical electrophoresis. Bambeck teaches that vertical electrophoresis typically provides cleaner separations and smoother flow of the macromolecular mixture. See col. 1, ll. 37-44. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Bambeck for the system of Hong and Harrington so as to have cleaner separations and smoother fluid flow.

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24. Claims 49-62 and 88-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong and Harrington as applied to claims 43, 46 and 86 above, and further in view of Manian et al (USP 5,137,609).

25. The references set forth all the limitations of the claims, but did not explicitly recite the step of detecting protein-binding interactions. Manian teaches the use of fluorescently labeled antibodies for the purpose of detecting the presence of certain proteins-binding interactions in biological samples. See col. 8, ll. 13-44. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Manian for the method of Hong and Harrington so that particular proteins may be specifically labeled and detected thereby increasing the selectivity of the protein assay.

26. Claims 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong and Harrington as applied to claim 43 above, and further in view of Allen et al (International Journal of Pharmaceutics 187, 1999, pp. 259-272).

27. The references set forth all the limitations of the claims, but did not explicitly recite the use of samples taken at different time points. Allen discloses that electrophoresis can be utilized for the determining the integrity of the protein sample under storage. See section 3.2 and fig. 8 where a non-degraded sample is compared with samples from different time points (i.e. after 6 weeks of storage). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Allen for the method of Hong and Harrington so as to extend the utility of the electrophoresis method to a determination of protein degradation.

Allowable Subject Matter

28. Claims 70-82 are allowed.

29. Claims 6, 7, 11-14, and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

30. Claim 42 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

31. If applicant explicitly specified that the set forth conductivity suppressor was present in claim 18, then claims 18-21 would also be objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

32. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 6 and 7, the prior art does not disclose nor render obvious all the limitations of claim 1 and further comprising a base solvent containing ethylene cyclic carbonate. With respect to claims 11-14, the prior art does not disclose nor render obvious all the limitations of claim 10 and further comprising any of the set forth mixtures conductivity enhancers. With respect to claims 18-21 (presuming the conductivity suppressor is explicitly recited as being present), the prior art does not disclose nor render obvious all the limitations of claim 1 and further comprising a conductivity suppressor from the list of claim 18. With respect to claim 33, the prior art does not disclose nor render obvious all the limitations of claim 23 and further comprising either of the set forth copolymers. With respect to claim 42, the prior art does not

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disclose all the cumulative limitations of claim 41 and 42 with particular attention to the top and bottom plates having substantially similar lengths and widths bridging the buffer chambers and the wick with the defined first and second ends. With respect to claims 70-82, the prior art does not disclose nor render obvious all the cumulative limitations of claim 70 with particular attention to the use of the first and second organic solvent having a first and second pH and placing the membrane in the first and second orientations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Friday from 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
February 6, 2007



KAJ K. OLSEN
PRIMARY EXAMINER